BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

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Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: *Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not be Infringed.* (67 Federal Register 65448 (October 24, 2002).

Dear Sir or Madam:

The Blue Cross and Blue Shield Association ("BCBSA") is pleased to submit comments on the proposed rule related to the Food and Drug Administration's (FDA's) requirements as published in the Federal Register on October 24, 2002 (67 Federal Register 65448). BCBSA represents the 42 independent, locally operated Blue Cross and Blue Shield Plans ("Plans") that collectively provide healthcare coverage for 84.7 million people – nearly 30 percent of all Americans. With health care costs on the rise once again, our Plans are looking for ways to continue to provide access to high quality care at an affordable price. Increased access to and use of generic drugs, where appropriate, is an important part of these efforts.

BCBSA applauds the Administration for addressing the critical issue of prescription drug affordability by issuing this proposed rule to help speed access to generics. While the proposed rule is an important first step, we believe that it can be strengthened to better ensure vigorous competition in the marketplace and make generic drugs available in the marketplace as soon as appropriate. We urge the Administration to consider the following recommendations and issue a final regulation as soon as possible.

Background: the Importance of Speeding Access to Generic Drugs

Prescription drugs have significantly extended life for many patients and contributed to their improved health status in the 20th century. Because pharmaceuticals are a key component in preventing and treating medical conditions, Plans offer pharmacy benefits to their members. However, the cost of drug benefit programs are high and account for a growing share of Plans'

total medical costs and our purchasers' premium dollars. Plans are experiencing up to 20 percent increases in prescription drug costs each year. These costs are expected to continue to grow rapidly. Plans face a constant challenge in providing affordable prescription drug coverage.

One important strategy Plans employ to help keep prescription drug coverage affordable is to encourage the use of generic drugs whenever possible. Generic drugs are subject to rigorous review by the FDA to ensure that they are high quality, therapeutically equivalent, and as safe and effective as their brand-name counterparts. Once approved for marketing, generic drugs offer consumers, employers and insurers significant savings compared to brand- name drugs.

Every day, the choice of generic drugs creates substantial savings for consumers. Typically, a generic drug enters the market priced 30 percent less than its brand counterpart. Within two years, as more generics enter the market, the average price of the generic version of a drug typically drops until it is 75 percent less than the brand.

As the Administration and Congress continue to work to develop a Medicare prescription drug benefit, a recent study found that increasing use of generic drugs could save $14 billion in 2003 and $250 billion during the next 10 years. The study, "Greater Use of Generics: A Prescription for Drug Cost Savings," conducted by Brandeis University, concludes that Medicare could achieve these savings by using generic pharmaceutical incentive techniques currently used in the private sector.

Although generic drugs have the same safety and effectiveness profile as their brand-name counterparts and can produce significant cost savings, they have a low rate of market penetration. Data from the Generic Pharmaceuticals Association indicates that generic drugs made up approximately 42 percent of all prescriptions dispensed at the retail level but accounted for only approximately 8 percent of the $141 billion spent on prescription drugs in 2000. Stated another way, brand name drugs, representing 58 percent of all prescriptions, accounted for 92 percent of the total retail cost of prescription drugs purchased in 2000.

This FDA proposed rule recognizes the important value generic drugs bring to the health care system. We applaud the Administration for issuing this proposed rule and offer the following specific recommendations to strengthen the FDA's ability to bring generic drugs to market more quickly.

BCBSA Comments on Proposed FDA Rule

Single 30-Month Stay Per Drug

BCBSA supports the FDA's goal of limiting the number of 30-month stays to only one per drug. BCBSA believes the FDA's goal is both reasonable and consistent with the purpose of the "Drug Price Competition and Patent Term Restoration Act," often called the "Hatch-

Waxman Act." This landmark legislation sought to balance increased intellectual property protection for branded drugs with a streamlined process of generic drug approval. Its dual purpose was: (1) to provide incentives for drug companies to invest in pharmaceutical research and development; and (2) to improve consumer access to more affordable generic medicines. Multiple 30-month stays, as described by the Federal Trade Commission (FTC) in its July 2002 Report, provide an extended monopoly on a given drug that the Act did not intend.

The draft regulation proposes to limit the availability of the one 30-month stay to patents filed prior to the filing of the Abbreviated New Drug Application (ANDA). BCBSA believes our mutual goal of speeding access to generic drugs would be better achieved by limiting the remedy to patents filed within 30 days of the original drug (New Drug Application or NDA) approval. This approach would likely limit litigation to those patents originally approved in the NDA and most directly related to the drug – such as patents on the drug product, formulation, or method of use that were granted by the U.S. Patent and Trademark Office at the time the NDA first was approved. Patent holders would still be permitted to litigate subsequently filed patents and seek injunctive relief when appropriate.

Effects of the Proposed Rule on the Timely Resolution of Patent Disputes

When a generic ANDA manufacturer files a paragraph IV certification (stating that it believes a patent is invalid, unenforceable, or will not be infringed) on the original patent(s) for an NDA drug product, it must also provide notice of its patent challenge to the patent/NDA holder, and in that notice lay out the rationale for its assertions of invalidity, unenforceability, or non-infringement. Under current law, if the brand-name company NDA holder and/or patent holder files a patent infringement lawsuit within 45 days of receipt of the notice, the FDA cannot approve the generic ANDA for a period of 30 months (or a longer or shorter period as determined by the court).

If the NDA holder files additional patents, the generic applicant must amend its ANDA with another paragraph IV certification. The FDA's proposed rule modifies its interpretation of the notice requirement so that submission of a second paragraph IV certification in an ANDA amendment would *not* trigger the notice requirements in section 505(j)(2)(B)(ii) of the Hatch-Waxman Act. By dropping the subsequent notice requirement, the proposed rule eliminates an important protection for ensuring that generic drugs get to market as soon as appropriate – namely, the 45-day period for filing subsequent patent infringement suits.

To remedy this situation, we urge the FDA to identify an administrative measure to address the timeliness of subsequent patent infringement suits. If, however, the implementation of such a measure is outside the scope of the FDA's existing authority, we recommend a legislative solution, as discussed later in this letter.

Implementation Timeframe

The proposed rule specifies that multiple 30-month stays could continue to apply to ANDA applications filed before the effective date of the rule (See 67 Federal Register 65457). Unfortunately, this approach would negate any significant effects of the proposed rule for many years. As the FDA is well aware, there are many "blockbuster" drugs for which patent protection is set to expire. These drugs should not enjoy the monopoly effect that multiple 30-month stays would bring. To address this concern, BCBSA recommends that only one 30-month stay be allowed for ANDAs filed before the effective date of the rule. We further recommend that if a given ANDA is already in the midst of a multiple 30-month stay at the time of the effective date of the final rule, that stay should be cancelled.

Patent Declaration Changes

BCBSA supports the FDA's proposed patent changes to require more detailed statements as part of its patent submission, including clarifying what patents must be – and must not be – listed with the FDA. However, we recommend that the patent declaration be expanded to require that brand manufacturers list all patents for which an infringement claim could reasonably be asserted and certify to the FDA that the listing is complete and accurate.

It is not unusual for brand manufacturers to list patents with the FDA as late as a year or more after a generic application has been filed because they currently are not required to list all patents with the FDA. Broadening the patent declaration requirement as we have recommended would do more to forestall unforeseen infringement suits than the proposed listing requirements by helping to prevent late filing of patent claims.

To help ensure that only appropriate patents are listed in the Orange Book, BCBSA further recommends that the FDA diligently enforce the requirement that patents be submitted to FDA within 30 days of the patent being **issued** and the requirement that a patent declaration be submitted to the FDA within 30 days of the date of product approval (or approval of a supplemental application for that product).

BCBSA understands that the FDA currently considers a patent to be timely submitted only if patent information is submitted to FDA within 30 days of the application's (or supplemental application) approval by the FDA. Under its current regulations, the FDA notifies applicants of their failure to submit patent information and withdraws their NDA only if patent information is not submitted within 30 days after receipt of such notice. (See 21 CFR 314.150(a)(2)(v)). However, current law clearly requires patent information concerning the drug, drug product, or a method of using the drug product be submitted to FDA within 30 days of the patent being **issued,** and an appropriate declaration concerning the scope of the patent be submitted within 30 days of the application's (or supplemental application) approval by the FDA.

Requiring patents be submitted within 30 days of being issued, coupled with more detailed patent declaration statements, is consistent with the intent of the Hatch-Waxman Act to require the timely submission of patent information and will provide generic companies with more certainty and allow them to make more informed decisions about patents that may be subject to challenge.

To summarize, BCBSA supports the FDA's efforts to speed access to generic drugs, but believes the proposed rule could go further to achieve this goal by incorporating the following recommendations:

- Make the 30-month stay remedy available for patents filed within 30 days of the NDA approval, rather than for patents filed prior to the ANDA filing;
- Adopt a measure to ensure that all patent infringement suits arising from a paragraph IV certification be filed in a timely manner;
- Ensure that only one 30-month stay per drug is available, both for ANDAs filed after the effective date of the final rule and for ANDAs filed before such a date. If a given ANDA is already in the midst of a multiple 30-month stay at the time of the effective date of the rule, that stay should be cancelled;
- Expand the proposed requirements regarding patent declarations to require a declaration that complete and accurate patent information has been filed; and
- Enforce the requirement that NDA holders submit patents to the FDA within 30 days of patent issuance and submit patent declarations to the FDA within 30 days of product approval (or approval of a supplemental application for that product).

BCBSA Supports Additional Legislative Action to Promote Timely Access to Generic Drugs

The FDA's proposed rule is a good first step toward a more competitive pharmaceutical market, but more should be done. We recognize that the FDA cannot address all of our concerns within a regulatory framework, so we offer the following recommendations for legislative action to promote vigorous competition in the prescription drug market by improving access to generic drugs.

Patent De-listings

BCBSA supports the ability of generic manufacturers to avoid being sued over frivolous patents by identifying a mechanism to correct existing patent listings/de-list frivolous patents from the Orange Book.

Timeframe for Bringing Patent Infringement Suits on Subsequently Listed Patents

Under the proposed rule, if an NDA/patent holder files additional patents after a generic applicant files its initial paragraph IV certification, submission of a second paragraph IV certification in an ANDA amendment would *not* trigger an additional notice requirement. By dropping the subsequent notice requirement, the proposed rule eliminates an important protection for ensuring that generic drugs get to market as quickly as possible – the 45-day window for bringing a patent infringement suit.

BCBSA recommends that measures be adopted to ensure that patent infringement suits – including those brought subsequent to the first paragraph IV certification – be filed in a timely manner. Such measures could include a 45-day statute of limitations provision (which would parallel the current timeframe for initiating a lawsuit after receipt of the notice requirement for the original paragraph IV certification) or other strategies to ensure that generic drugs get to market as soon as appropriate.

180-day Exclusivity Period

Current law grants a 180-day period of market exclusivity to the first generic applicant who certifies that the patents on the brand product it intends to copy are either invalid, unenforceable, or will not be infringed by the manufacturing and marketing of a generic version of the drug. However, the 180-day period does not begin until the first applicant goes to market or litigation surrounding the certification is resolved. In the interim, all other generic applicants are kept out of the market. As documented in the FTC report, there have been situations in the past in which brand companies paid the first generic applicant to stay out of the market, preventing competition among generic companies and delaying consumer access to generics for an extended period.

BCBSA supports the following legislative changes to ensure that the 180-day exclusivity period more fully realizes its promise of bringing generic drugs to market more quickly:

- Establish an appellate court decision or the date of a settlement agreement or consent decree that includes a finding of invalidity or non-infringement as "triggers" for 180-day exclusivity period for the first-to-file a paragraph IV certification generic applicant, providing certainty for the applicant.

  The change to use of the appellate court as a trigger is needed to preserve one of the primary incentives for generic companies to challenge a patent, i.e., 180 days of market exclusivity. Currently, the 180-day market exclusivity trigger is a district court decision and the 180-day exclusivity period can run out before the first company to file an application containing a paragraph IV certification enters the market. The current approach thus eliminates one of the primary incentives to challenge a patent. The date of a settlement agreement should also be a triggering event for other generic companies to enter the market 180 days after a settlement is reached. Both these measures will serve to promote patent challenges and earlier entry of generic products into the market.

- Establish that a generic company forfeits the 180-day exclusivity period under the following conditions:
  - The applicant fails to go to market within 60 days of an appellate court decision or final FDA approval (if no patent infringement suit is filed);
  - The generic drug fails to receive approval within 30 months;
  - The generic applicant changes its patent certification from a paragraph IV to a paragraph III certification;
  - The generic applicant fails to challenge a new patent that is listed in the Orange Book; and
  - The FTC finds the applicant engaged in unlawful conduct (such as an agreement with a brand manufacturer to stay out of the market).
- Award the 180-day exclusivity period to the second-to-file generic company if such forfeiture occurs. If the second-to-file generic applicant forfeits the exclusivity, all generics with an approved application should be able to go to market immediately.

BCBSA appreciates this opportunity to submit comments on the proposed rule and commends the FDA on its significant role in ensuring timely access to generic drugs. BCBSA supports FDA's continued regulation in this area and is hopeful that this proposed rule will soon be final and lead to a continued legislative dialogue on issues and areas where timely access to generic drugs may be improved.

Questions concerning these comments may be directed to Stephanie Aldrich at 202.626.4817 or stephanie.aldrich@wro.bcbsa.com.

Sincerely,

Alissa Fox

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